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Bimekizumab efficacy and safety through two years in patients with moderate to severe plaque psoriasis: Analysis of pooled data from five phase 3/3b clinical trials

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Disclosures

- **KBG:** Consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma; research support from AbbVie, BMS, Celgene, Eli Lilly, Janssen, Novartis and UCB Pharma.
- **AWA:** Has served as a research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, EPI, Incyte, LEO Pharma, UCB Pharma, Janssen, Eli Lilly, Nimbus, Novartis, Ortho Dermatologics, Sun Pharma, Sanofi, Regeneron and Pfizer.
- **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen, Ortho Dermatologics, Regeneron, and UCB Pharma and is a consultant for Aditum Bio, Almirall, AltruBio, AnaptysBio, Arcutis, Aristeia Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy and Verrica.
- **AB:** Has served as a speaker, scientific adviser and/or clinical study investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, EcoR1, Eli Lilly, Evommune, Forte, Galderma, Incyte, Janssen, Landos, LEO Pharma, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, UCB Pharma, Vibliome and Xencor.
- **CP:** Consulting fees and /or grants from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, GSK, Janssen Cilag, LEO Pharma, Eli Lilly, Novartis, Pierre Fabre, Pfizer, Sanofi Regeneron and UCB Pharma.
- **MW, VV, CM, NNG, DD:** Employees and shareholders of UCB Pharma.
- **DT:** Honoraria for participation on advisory boards, as a speaker and for consultancy from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly, Galapagos, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Samsung, Sandoz, Sanofi Genzyme, Sun Pharma and UCB Pharma; research grants received from LEO Pharma and Novartis.

Acknowledgements

This study was funded by UCB Pharma. We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany for publication coordination and Alexa Holland, MSc, Costello Medical, Manchester, UK, for medical writing and editorial assistance. All costs associated with development of this presentation were funded by UCB Pharma.

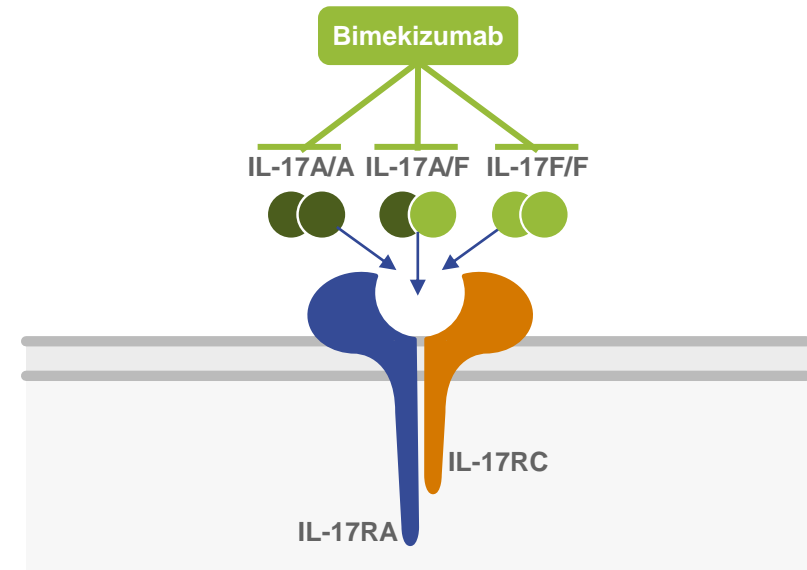
Background

- Plaque psoriasis is a chronic disease requiring long-term management; therefore, it is important to understand the long-term efficacy and safety of treatments¹
- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits both interleukin (IL)-17A and IL-17F^{2,3}
- In phase 3 clinical trials, BKZ provided substantial clinical improvements in patients with moderate to severe plaque psoriasis, with no unexpected safety findings^{4–7}

Objectives

- Assess the long-term maintenance of response with BKZ through two years of treatment, using the largest available two-year data pool, in patients with moderate to severe plaque psoriasis
- Evaluate the long-term safety of BKZ through two years of treatment in patients who received ≥ 1 dose of BKZ in five phase 3/3b trials

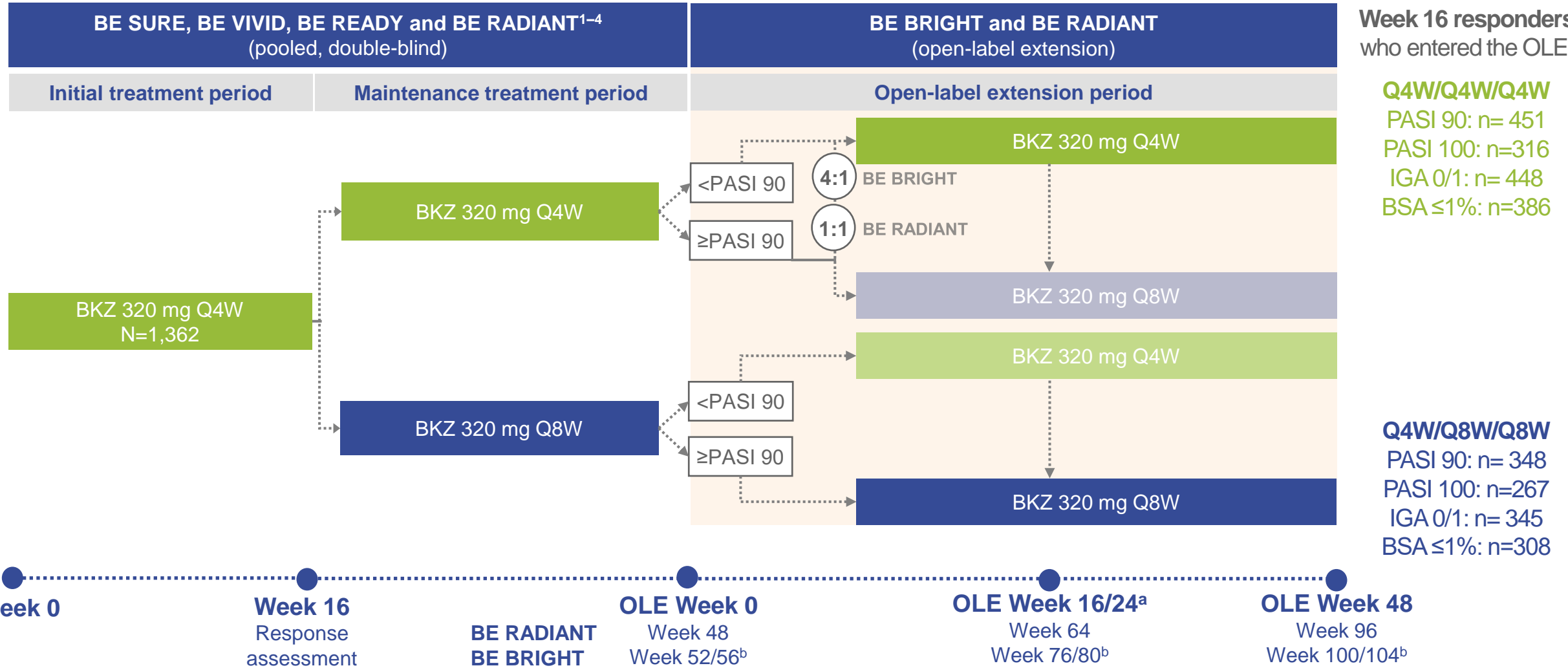
Inhibition of IL-17 with bimekizumab^a



[a] Adapted from: Patel D et al. Ann Rheum Dis 2013;72(Suppl 2):ii116–23. 1. Gisoni P et al. Int J Mol Sci 2017;18:2427; 2. Adams R et al. Front Immunol 2020;11:1894; 3. Glatt S et al. Ann Rheum Dis 2018;77:523–32; 4. Reich K et al. Lancet 2021;397:487–98; 5. Gordon K et al. Lancet 2021;397:475–86; 6. Warren R et al. New Eng J Med 2021;385:130–41; 7. Reich K et al. New Eng J Med 2021;385:142–52. BKZ: bimekizumab; Ig: immunoglobulin; IL: interleukin.

Study Design Overview

Patients included in the efficacy analyses



[a] Dose switch: BE BRIGHT OLE Week 24, for patients achieving PASI 90 at investigator discretion; BE RADIANT OLE Week 16 or next scheduled visit, dose switch added via protocol amendment; [b] BE VIVID Week 52 and BE SURE and BE READY Weeks 52 and 56 were not included in the pooled analysis. 1. Reich K et al. Lancet 2021;397:487–98; 2. Warren R et al. New Eng J Med 2021;385:130–41; 3. Gordon K et al. Lancet 2021;397:475–86; 4. Reich K et al. New Eng J Med 2021;385:142–52. BKZ: bimekizumab; BSA: body surface area; IGA 0/1: score of 0 (clear) or 1 (almost clear) with ≥2-category improvement relative to baseline in Investigator's Global Assessment, scored on a 5-point scale; OLE: open-label extension; PASI 90/100: ≥90/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every four weeks; Q8W: every eight weeks.

Analysis Populations

Efficacy Analysis

Includes patients who:

- Achieved PASI 90, PASI 100, IGA 0/1 or BSA \leq 1% at Week 16 of the BE SURE, BE READY, BE VIVID or BE RADIANT phase 3/3b trials
- Entered the BE RADIANT or BE BRIGHT OLEs
- Received continuous BKZ dosing from Week 16 through the maintenance period and the OLE (Q4W/Q4W/Q4W or Q4W/Q8W/Q8W)

Safety Analysis

Includes patients who:

- Received \geq 1 dose of BKZ during any of the phase 3 trials (BE VIVID, BE READY, BE SURE, BE RADIANT) or their OLEs (BE BRIGHT or BE RADIANT)

Week 16 Responders: Demographics and Baseline Disease Characteristics

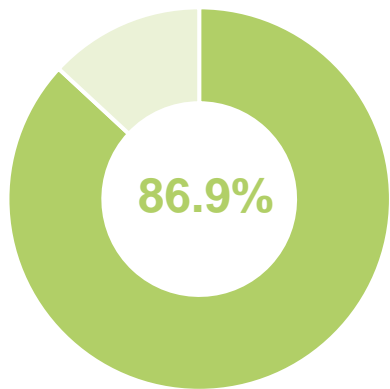
Week 16 responders who enrolled in BE BRIGHT or the BE RADIANT OLE^a

	PASI 90 responders (N=995)	PASI 100 responders (N=719)	IGA 0/1 responders (N=985)	BSA ≤1% responders (N=857)	All BKZ-randomised patients N=1,362
Age (years), mean ± SD	45.0 ± 13.5	45.1 ± 13.3	45.1 ± 13.5	45.2 ± 13.5	45.1 ± 13.6
Male, n (%)	695 (69.8)	497 (69.1)	692 (70.3)	591 (69.0)	949 (69.7)
Caucasian, n (%)	872 (87.6)	642 (89.3)	871 (88.4)	756 (88.2)	1,188 (87.2)
Weight (kg), mean ± SD	89.1 ± 20.8	87.9 ± 19.6	89.4 ± 20.8	88.6 ± 20.4	89.7 ± 21.9
BMI, mean ± SD	29.7 ± 6.4	29.3 ± 6.0	29.7 ± 6.4	29.6 ± 6.3	29.9 ± 6.8
Duration of psoriasis (years), mean ± SD	18.2 ± 12.6	18.2 ± 12.6	18.3 ± 12.5	18.2 ± 12.7	18.2 ± 12.6
PASI, mean ± SD	21.2 ± 7.7	20.8 ± 7.3	21.0 ± 7.6	20.7 ± 7.4	20.7 ± 7.6
BSA (%), mean ± SD	26.9 ± 16.0	25.8 ± 15.0	26.5 ± 15.7	25.8 ± 15.1	26.0 ± 15.6
IGA, n (%)					
3: moderate	652 (65.5)	476 (66.2)	648 (65.8)	574 (67.0)	896 (65.8)
4: severe	341 (34.3)	242 (33.7)	334 (33.9)	282 (32.9)	463 (34.0)
DLQI, mean ± SD	10.7 ± 6.4	10.9 ± 6.5	10.7 ± 6.4	10.8 ± 6.4	10.5 ± 6.4
Any prior systemic therapy, n (%)	772 (77.6)	568 (79.0)	760 (77.2)	671 (78.3)	1,038 (76.2)
Prior biologic therapy, n (%) ^b					
anti-TNF	156 (15.7)	111 (15.4)	152 (15.4)	135 (15.8)	208 (15.3)
anti-IL-17	210 (21.1)	155 (21.6)	205 (20.8)	182 (21.2)	270 (19.8)
anti-IL-23	52 (5.2)	41 (5.7)	53 (5.4)	49 (5.7)	N/a
anti-IL-12/23	59 (5.9)	40 (5.6)	56 (5.7)	49 (5.7)	N/a

[a] All BKZ-treated patients received BKZ 320 mg Q4W through Week 16 of the feeder studies. Data are reported for all patients with a response at Week 16 who enrolled in BE BRIGHT or the BE RADIANT OLE, regardless of dosing regimen; [b] Patients with multiple prior biologic use included in n (%). BMI: body mass index; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA 0/1: score of 0 (clear) or 1 (almost clear) with ≥2-category improvement relative to baseline in Investigator's Global Assessment, scored on a 5-point scale; IL: interleukin; N/a: not applicable; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; SD: standard deviation; TNF: tumor necrosis factor.

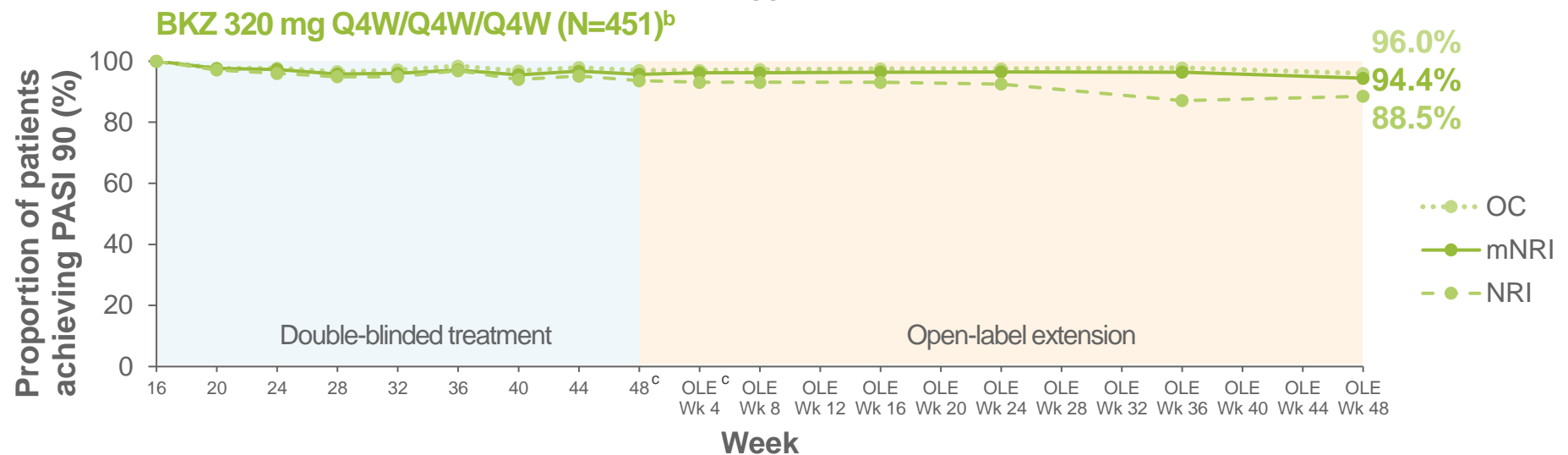
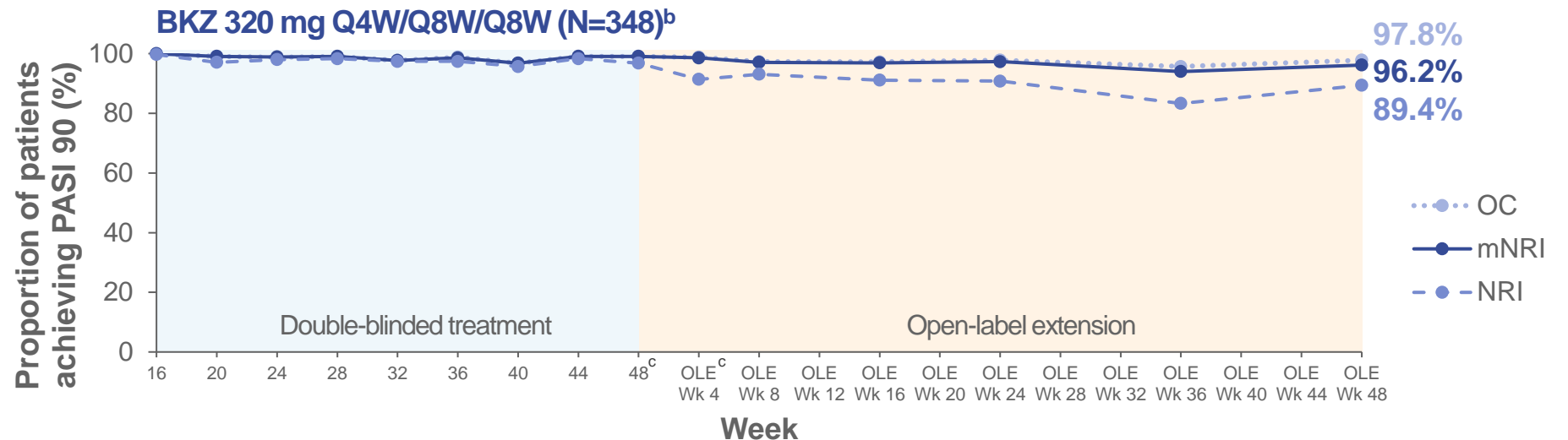
Maintenance of PASI 90 Responses Through Two Years (Pooled; mNRI, NRI, OC)

Week 16:
86.9% (1,184/1,362) of BKZ-treated patients achieved PASI 90 during the initial period (NRI)^a



BKZ 320 mg Q4W (N=1,362)

PASI 90 in Week 16 PASI 90 responders

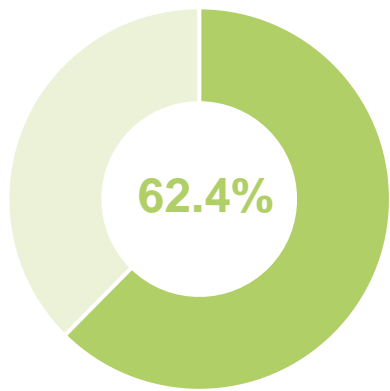


[a] Response at Week 16 in patients randomized to BKZ 320 mg Q4W at baseline (NRI); [b] Data reported for patients with a response at Week 16 who received continuous maintenance dosing regimens; [c] The BE READY and BE SURE feeder studies ran for 56 weeks, BE VIVID ran for 52 weeks, and BE RADIANT ran for 48 weeks; to pool the data across all four studies, feeder study data from Week 52–56 were not included. BKZ: bimekizumab; mNRI: modified non-responder imputation (patients with missing data following treatment discontinuation due to lack of efficacy were considered non-responders; multiple imputation methodology was used for other missing data); NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI 90: $\geq 90\%$ improvement from baseline in Psoriasis Area and Severity Index; Q4W: every four weeks; Q8W: every eight weeks.

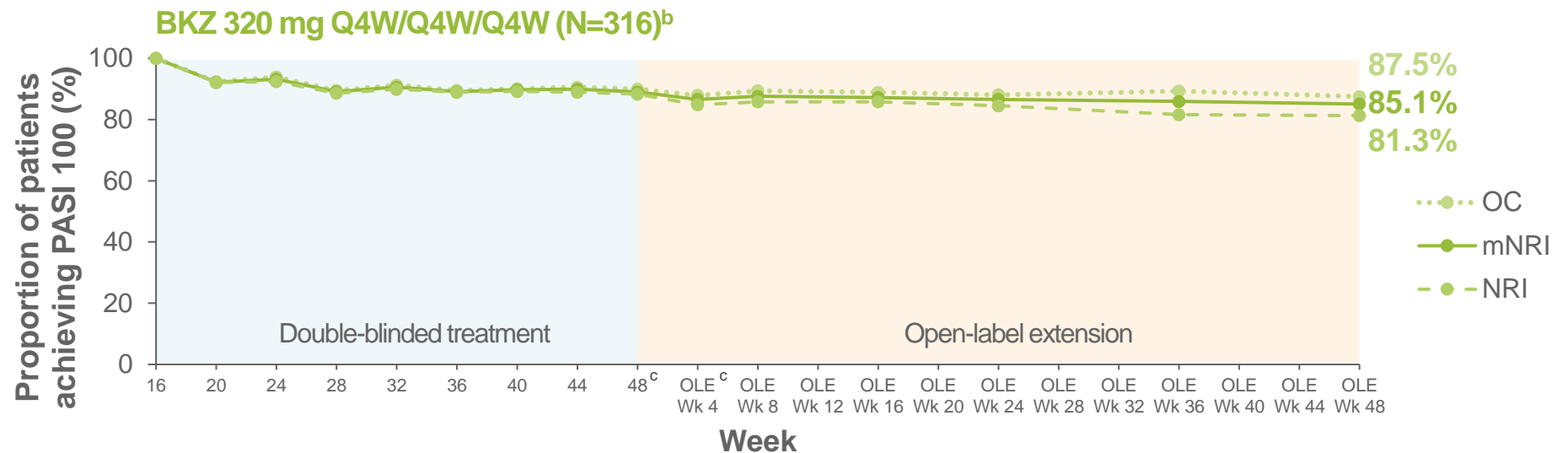
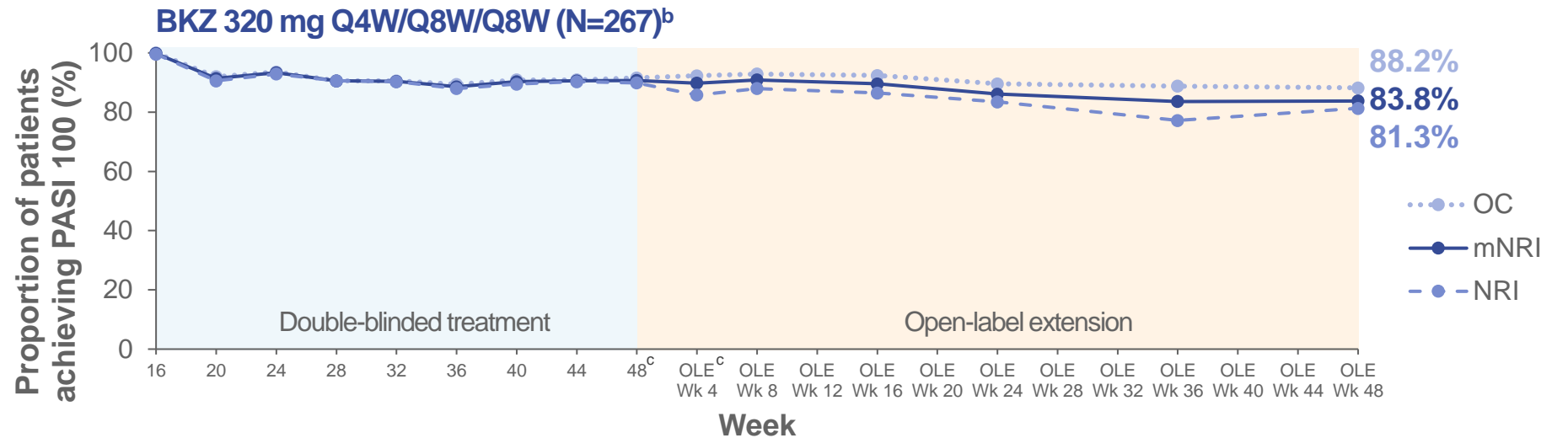
Maintenance of PASI 100 Responses Through Two Years (Pooled; mNRI, NRI, OC)

PASI 100 in Week 16 PASI 100 responders

Week 16:
62.4% (850/1,362) of
 BKZ-treated patients achieved
 PASI 100 during the initial
 period (NRI)^a



BKZ 320 mg Q4W
(N=1,362)

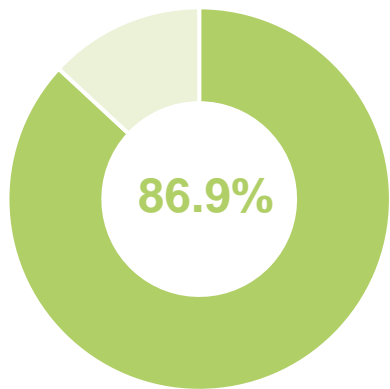


[a] Response at Week 16 in patients randomized to BKZ 320 mg Q4W at baseline (NRI); [b] Data reported for patients with a response at Week 16 who received continuous maintenance dosing regimens; [c] The BE READY and BE SURE feeder studies ran for 56 weeks, BE VIVID ran for 52 weeks, and BE RADIANT ran for 48 weeks; to pool the data across all four studies, feeder study data from Week 52–56 were not included. BKZ: bimekizumab; mNRI: modified non-responder imputation (patients with missing data following treatment discontinuation due to lack of efficacy were considered non-responders; multiple imputation methodology was used for other missing data); NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every four weeks; Q8W: every eight weeks.

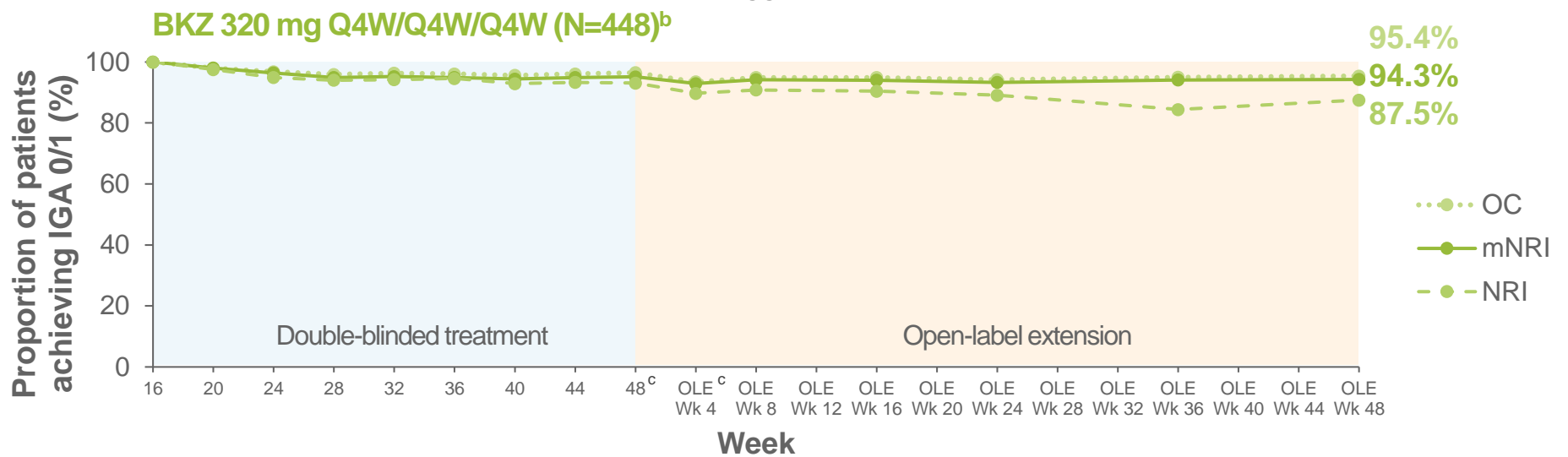
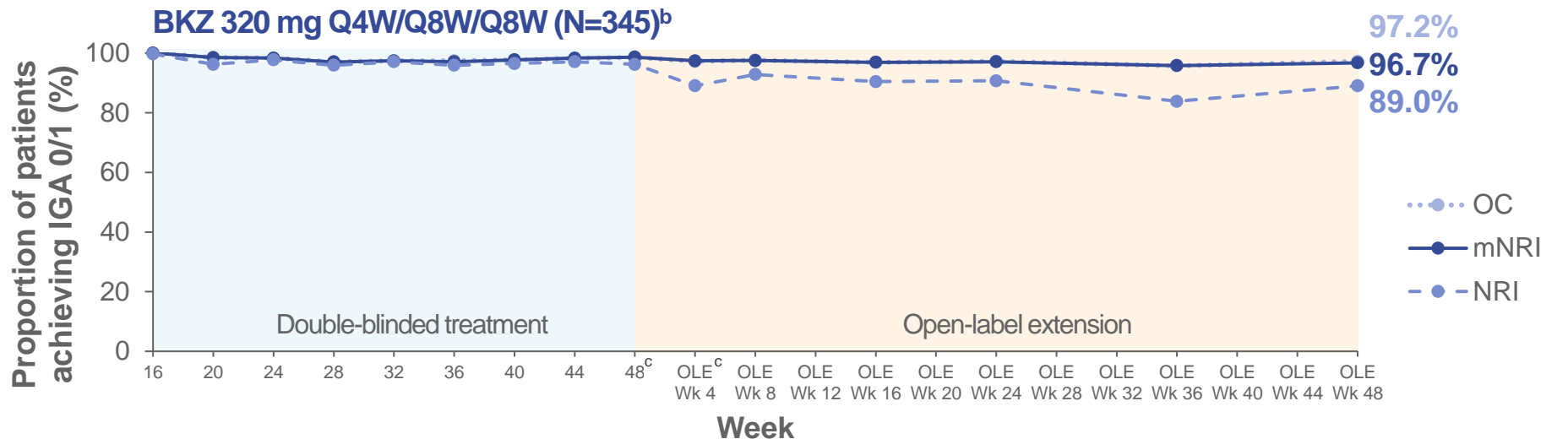
Maintenance of IGA 0/1 Responses Through Two Years (Pooled; mNRI, NRI, OC)

IGA 0/1 in Week 16 IGA 0/1 responders

Week 16:
86.9% (1,184/1,362) of BKZ-treated patients achieved IGA 0/1 during the initial period (NRI)^a



BKZ 320 mg Q4W (N=1,362)

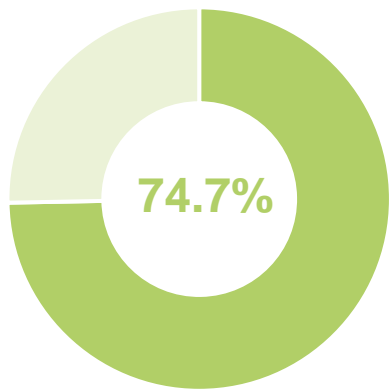


[a] Response at Week 16 in patients randomized to BKZ 320 mg Q4W at baseline (NRI); [b] Data reported for patients with a response at Week 16 who received continuous maintenance dosing regimens; [c] The BE READY and BE SURE feeder studies ran for 56 weeks, BE VIVID ran for 52 weeks, and BE RADIANT ran for 48 weeks; to pool the data across all four studies, feeder study data from Week 52–56 were not included. BKZ: bimekizumab; IGA 0/1: score of 0 (clear) or 1 (almost clear) with ≥2-category improvement relative to baseline in Investigator's Global Assessment, scored on a 5-point scale; mNRI: modified non-responder imputation (patients with missing data following treatment discontinuation due to lack of efficacy were considered non-responders; multiple imputation methodology was used for other missing data); NRI: non-responder imputation; OC: observed case; OLE: open-label extension; Q4W: every four weeks; Q8W: every eight weeks.

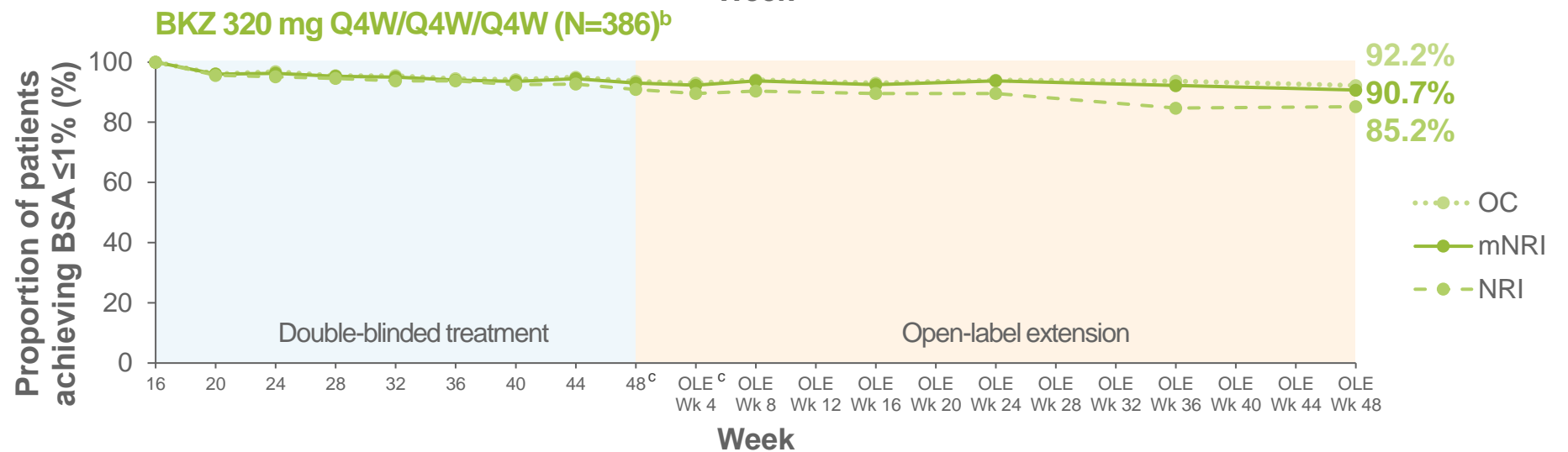
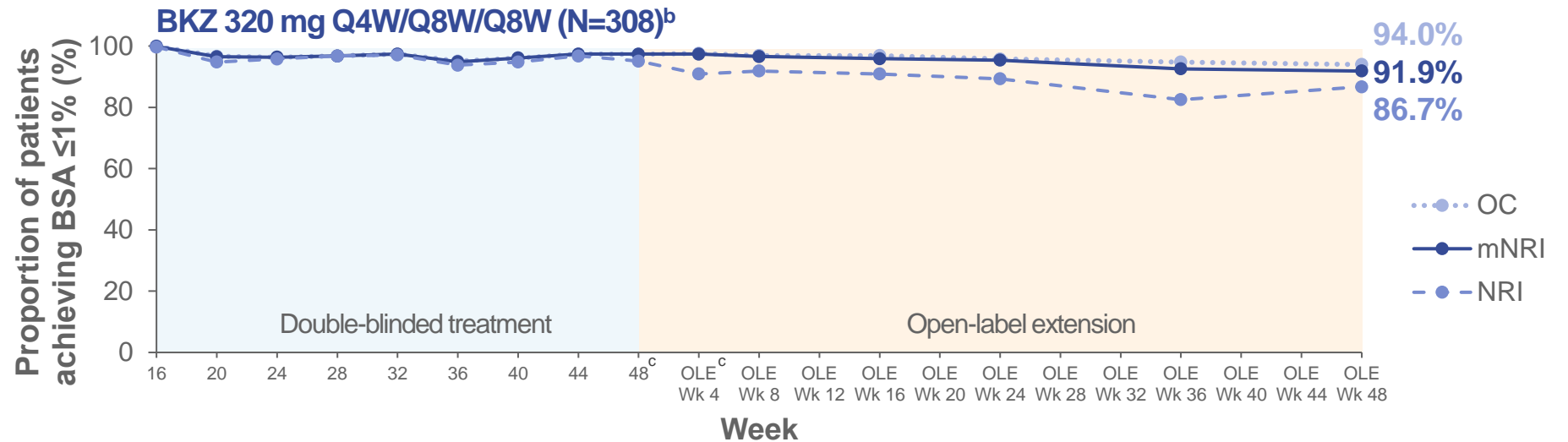
Maintenance of BSA $\leq 1\%$ Responses Through Two Years (Pooled; mNRI, NRI, OC)

BSA $\leq 1\%$ in Week 16 BSA $\leq 1\%$ responders

Week 16:
74.7% (1,017/1,362) of BKZ-treated patients achieved BSA $\leq 1\%$ during the initial period (NRI)^a



BKZ 320 mg Q4W (N=1,362)



[a] Response at Week 16 in patients randomized to BKZ 320 mg Q4W at baseline (NRI); [b] Data reported for patients with a response at Week 16 who received continuous maintenance dosing regimens; [c] The BE READY and BE SURE feeder studies ran for 56 weeks, BE VIVID ran for 52 weeks, and BE RADIANT ran for 48 weeks; to pool the data across all four studies, feeder study data from Week 52–56 were not included. BKZ: bimekizumab; BSA: body surface area; mNRI: modified non-responder imputation (patients with missing data following treatment discontinuation due to lack of efficacy were considered non-responders; multiple imputation methodology was used for other missing data); NRI: non-responder imputation; OC: observed case; OLE: open-label extension; Q4W: every four weeks; Q8W: every eight weeks.

Two-Year Pooled Safety from Five Phase 3/3b Clinical Trials

	BKZ 320 mg Q4W (N=2,025) PY = 2,329 EAIR/100 PY (95% CI)	BKZ 320 mg Q8W (N=1,576) PY = 1,471 EAIR/100 PY (95% CI)	Phase 3 BKZ Total (N=2,186) PY = 3,796 EAIR/100 PY (95% CI)
Any TEAE	225.2 (214.4, 236.4)	149.9 (140.4, 159.8)	192.7 (184.2, 201.5)
Severe TEAEs	5.5 (4.6, 6.6)	5.4 (4.3, 6.8)	5.3 (4.6, 6.1)
TEAEs leading to discontinuation	3.8 (3.0, 4.7)	2.4 (1.7, 3.3)	3.2 (2.7, 3.9)
Treatment-related TEAEs^a	45.7 (42.4, 49.0)	30.8 (27.7, 34.2)	36.1 (33.8, 38.5)
Serious TEAEs	6.1 (5.1, 7.2)	5.7 (4.5, 7.0)	5.9 (5.1, 6.7)
TEAEs leading to death	0.3 (0.1, 0.6)	0.3 (0.1, 0.7)	0.3 (0.1, 0.5)
Most common TEAEs^b			
Nasopharyngitis	22.0 (19.9, 24.2)	15.5 (13.5, 17.9)	18.4 (17.0, 20.0)
Oral candidiasis	17.1 (15.4, 19.0)	10.5 (8.9, 12.4)	13.0 (11.8, 14.3)
Upper respiratory tract infection	8.8 (7.6, 10.2)	7.3 (5.9, 8.8)	7.8 (6.9, 8.8)

The incidences of overall and treatment-related TEAEs were lower with bimekizumab Q8W dosing compared with Q4W.

Includes all patients who received BKZ during any of the phase 3 trials (BE VIVID, BE READY, BE SURE, BE RADIANT) or their OLEs (BE BRIGHT or BE RADIANT); BE BRIGHT data cut-off: Nov 9 2020; BE RADIANT data cut-off Apr 20 2021. TEAEs were assigned to the dose most recently received prior to the date of onset of the TEAE. Patients who received both BKZ 320 mg Q4W and Q8W at different times in the trials are included in the population count of both treatment groups, but only once in the BKZ total group. TEAEs coded according to the Medical Dictionary for Regulatory Activities v19.0. [a] Assessed as related to treatment by the investigator; [b] The three most frequently occurring TEAEs in the BKZ total group. BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; OLE: open-label extension; PY: patient-years; Q4W: every four weeks; Q8W: every eight weeks; TEAE: treatment-emergent adverse event.

Two-Year Pooled Safety from Five Phase 3/3b Clinical Trials: Safety Topics of Interest (1/2)

	BKZ 320 mg Q4W (N=2,025) PY = 2,329 EAIR/100 PY (95% CI)	BKZ 320 mg Q8W (N=1,576) PY = 1,471 EAIR/100 PY (95% CI)	Phase 3 BKZ Total (N=2,186) PY = 3,796 EAIR/100 PY (95% CI)
Serious infections	1.4 (1.0, 2.0)	0.9 (0.5, 1.5)	1.2 (0.9, 1.6)
Corona virus infections ^a	0.6 (0.3, 1.0)	1.7 (1.1, 2.5)	1.0 (0.7, 1.4)
Fungal infections			
<i>Candida</i> infections	19.9 (18.0, 21.9)	11.9 (10.1, 13.9)	15.0 (13.6, 16.4)
Oral candidiasis	17.1 (15.4, 19.0)	10.5 (8.9, 12.4)	13.0 (11.8, 14.3)
Fungal infections NEC	4.2 (3.4, 5.2)	3.4 (2.5, 4.5)	3.7 (3.1, 4.3)
<i>Tinea</i> infections	3.2 (2.5, 4.1)	2.9 (2.1, 4.0)	2.9 (2.4, 3.5)
Adjudicated MACE	0.5 (0.2, 0.8)	0.3 (0.1, 0.8)	0.4 (0.2, 0.7)
Serious hypersensitivity reactions ^b	0.1 (0.0, 0.4)	0.1 (0.0, 0.5)	0.1 (0.0, 0.3)

98.1% (415/423) of patients with oral candidiasis reported a mild or moderate infection. There were no serious cases of oral candidiasis. Five led to discontinuation.

There were two cases of serious fungal infection: one case of systemic candidiasis (diabetic patient with recurrent UTIs treated with broad spectrum antibiotics, obstructive uropathy and recent urinary tract instrumentation) and one case of oesophageal candidiasis. Both cases resolved with treatment.

BE BRIGHT data cut-off: Nov 9 2020; BE RADIANT data cut-off Apr 20 2021. Patients who received both BKZ 320 mg Q4W and Q8W at different times in the trials are included in the population count of both treatment groups, but only once in the BKZ total group. TEAEs coded according to the Medical Dictionary for Regulatory Activities v19.0. [a] All corona virus infections, including and not limited to, Covid-19 infection; [b] There were no anaphylactic reactions associated with BKZ reported. BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; MACE: major adverse cardiac event; NEC: not elsewhere classified; PY: patient-years; Q4W: every four weeks; Q8W: every eight weeks; UTI: urinary tract infection.

Two-Year Pooled Safety from Five Phase 3/3b Clinical Trials: Safety Topics of Interest (2/2)

	BKZ 320 mg Q4W (N=2,025) PY = 2,329 EAIR/100 PY (95% CI)	BKZ 320 mg Q8W (N=1,576) PY = 1,471 EAIR/100 PY (95% CI)	Phase 3 BKZ Total (N=2,186) PY = 3,796 EAIR/100 PY (95% CI)
Adjudicated SIB^a	0.1 (0.0, 0.3)	0.0 (0.0, 0.0)	0.1 (0.0, 0.2)
Inflammatory bowel disease	0.2 (0.0, 0.4)	0.1 (0.0, 0.4)	0.1 (0.0, 0.3)
Colitis ulcerative	0.1 (0.0, 0.3)	0.0 (0.0, 0.0)	0.1 (0.0, 0.2)
Crohn's disease	0.0 (0.0, 0.2)	0.1 (0.0, 0.4)	0.0 (0.0, 0.2)
Colitis	0.0 (0.0, 0.2)	0.0 (0.0, 0.0)	0.0 (0.0, 0.1)
Neutropenia TEAEs	0.9 (0.5, 1.3)	0.4 (0.2, 0.9)	0.6 (0.4, 0.9)
Malignancies	0.8 (0.5, 1.2)	0.8 (0.4, 1.4)	0.8 (0.5, 1.1)
Malignancies excluding NMSC	0.3 (0.1, 0.7)	0.5 (0.2, 1.1)	0.4 (0.2, 0.7)
NMSC	0.4 (0.2, 0.8)	0.3 (0.1, 0.7)	0.4 (0.2, 0.6)
Any hepatic TEAEs	4.0 (3.2, 4.9)	3.3 (2.4, 4.3)	3.5 (3.0, 4.2)
Liver function analyses ^b	3.4 (2.7, 4.3)	2.6 (1.9, 3.6)	2.9 (2.4, 3.5)
ALT or AST elevations^c			
>x3 upper limit of normal	2.7 (2.1, 3.5)	2.0 (1.3, 2.9)	2.3 (1.9, 2.9)
>x5 upper limit of normal	0.6 (0.4, 1.1)	0.6 (0.3, 1.2)	0.6 (0.4, 0.9)

BE BRIGHT data cut-off: Nov 9 2020; BE RADIANT data cut-off: Apr 20 2021. Patients who received both BKZ 320 mg Q4W and Q8W at different times in the trials are included in the population count of both treatment groups, but only once in the BKZ total group. TEAEs coded according to the Medical Dictionary for Regulatory Activities v19.0. [a] One suicide attempt and one suicidal ideation; [b] Liver function analyses included the following preferred terms reported as adverse events: hepatic enzyme increased, AST increased, gamma-glutamyl transferase increased, ALT increased, liver function test increased, transaminases increased, blood bilirubin increased, and liver function test abnormal; [c] Not all hepatic laboratory parameter elevations reported as adverse events. Total time at risk was recorded from last laboratory assessment (BKZ Q4W: 2,331 PY; BKZ Q8W: 1,469 PY; BKZ Total: 3,797 PY). ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; NMSC: non-melanoma skin cancer; PY: patient-years; Q4W: every four weeks; Q8W: every eight weeks; SIB: suicidal ideation and behavior; TEAE: treatment-emergent adverse event.

Conclusions

- In these pooled analyses, using the largest available two-year BKZ data pool to date, Week 16 clinical response rates were maintained through two years of BKZ treatment
- PASI 90, PASI 100, IGA 0/1 and BSA $\leq 1\%$ response rates were maintained with both BKZ continuous Q4W or Q8W maintenance dosing regimens
- BKZ continued to be well-tolerated with longer-term use (2,186 patients; 3,796 PY); there were no unexpected safety findings through two years and TEAEs were consistent with individual study results reported through one year^{1–4}